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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,937	12/21/2001	Keith D. Allen	R-632 CIP	7301

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,937	ALLEN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,10-13,23-34 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *1, 2, 10-13, 23-33 and 38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-9, 14-22 and 35-37 have been canceled. Claims 1, 2, 10-13, 23-34 and 38-40 remain pending.

Applicant's arguments filed 7-19-06 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment to the description of Fig. 2A-2B has been entered.

Election/Restrictions

Claims 1, 2, 10-13, 23-33 and 38-40 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim 34 is under consideration in the instant office action.

Claim Rejections - 35 USC § 101

Claim 34 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Claim 34 is directed toward a transgenic mouse whose genome comprises a homozygous disruption of the FPR-RS4 gene, wherein the transgenic mouse exhibits, relative to a wild-type control mouse, at least one phenotype selected from the group consisting of enlarged heart, increased heart weight, increased heart to body weight ratio and myocardial fibrosis.

The specification teaches making FPR-RS4 -/- mice (pg 53). The specification suggests using the mice as a model of disease, specifically as a model for behavioral, neurological, psychoneurological, psychotic phenotypes, and increased pain threshold (pg 20-22; pg 22, lines 17-21). However, the specification does not disclose one specific behavioral, neurological, neuropsychological or psychotic disease or disease related to increased pain threshold in humans linked to a disruption in FPR-RS4. The homozygous mice were tested in an "open field test" (pg 57), "rotarod test" (pg 58) and "metrazol test" (pg 58). FPR-RS4 -/- mice spent less time in the open field, decreased time on the rod in the "rotarod test" and required increased metrazol to induce a seizure. However, the results of the tests do not correlate to a useful phenotype because the tests are not specific to a disease linked to a disruption in an FPR-RS4 gene. The results of the tests are also not statistically significant because the number of mice tested is not disclosed. The mice claimed cannot be used to determine compounds that modulate FPR-RS4 expression because FPR-RS4 is not expressed in the mice. Using the mice to determining whether a particular phenotype is ameliorated is not a specific or substantial utility because the specification does not link the phenotype to any specific disease or to a disease caused by a disruption in humans. The specification does not identify any compounds that alter neurological, neuropsychological, or psychotic phenotypes using the mice. Thus, the specification does not provide a specific or substantial use for a mouse as claimed, specifically exhibiting "decreased time spent in a central region of an open field test", impaired motor coordination or balance or ataxia, decreased performance on an accelerating rotarod, decreased

susceptibility to seizures and heart abnormalities as described in the specification. In particular, the specification does not provide any use for the mouse claimed having the heart abnormalities now claimed.

Applicants point to an NIH report from 2005 and argue those of skill would readily appreciate why the knockout mice claimed are useful to define the function of the disrupted gene, regardless of whether the inventor has described any specific phenotypes of the knockout mouse. Applicants' argument is not persuasive. First, the NIH report was not available until 2005 and cannot be used to establish what was "well-established" at the time of filing. Second, the NIH report suggests knockout mice may be models of disease; however, a mouse exhibiting "decreased time spent in a central region of an open field test", impaired motor coordination or balance or ataxia, decreased performance on an accelerating rotarod, decreased susceptibility to seizures and heart abnormalities as described in the specification is not a model of any disease condition in humans. Third, the NIH report states knockout mice can be used to elucidate gene function. The NIH report does not state all knockout mice will determine the function of the gene. Overall, applicants do not provide the blaze marks for those of skill to perform any further research on the FPR-RS4 gene by teaching the ligands, agonists or antagonists of FPR-RS4, for example, or providing any specific assays for characterizing the FPR-RS4 gene within the realm of heart abnormalities. In fact, applicants used the mice in expression analysis and phenotype analysis tests, but applicants have not determined the function of the gene. Simply using the mice for further research of the FPR-RS4 gene is not a specific or substantial utility and would

require further characterization of the mouse itself, which does not constitute a substantial utility.

Applicants argue the claimed invention has been delivered to a large pharmaceutical company and that three pharmaceutical companies use the DeltaBase. Applicants' arguments are not persuasive. The claims are to a mouse, not the DeltaBase; therefore, use of a database is irrelevant to the claimed mouse. Furthermore, "delivery" to pharmaceutical companies at an undisclosed time is not adequate to indicate that applicants knew how to use the mice claimed at the time of filing. First, applicants do not establish the mice were delivered to pharmaceutical companies prior to the time of filing. Second, the pharmaceutical company may have determined how to use the mice and not applicants.

Applicants argue as a result of the disruption, the transgenic mouse exhibits heart abnormalities and can be used to study the association of FPR-RS4 to heart disease. Therefore, applicants conclude the mouse has a specific utility, i.e. specific to the FPR-RS4 disruption. Applicants' arguments are not persuasive. It cannot be envisioned how to perform such further research. Please point to one assay that will elucidate the role of FPR-RS4 in heart disease. Furthermore, the phenotypes observed may have been a result of the mixed genome of the mice and not the disruption of the FPR-RS4 gene itself. Finally, the phenotypes observed may be a result of other genes compensating for the disruption of FPR-RS4. Assuming arguendo, that the mouse claimed does have a specific utility in studying the association of FPR-RS4 with the heart disease, the asserted utility does not have substantial utility because the

specification does not teach how to perform such further research and because such further research would require further analysis of the mouse itself.

Claim Rejections - 35 USC § 112

Claim 34 remains rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use mice having abnormal pain threshold.

Applicants' arguments regarding how to use the mouse claimed are addressed above.

The other enablement rejections have been withdrawn in view of the amendment.

Indefiniteness

Claim 34 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of what applicants consider "FPR-RS4" genes cannot be determined. The specification defines the term as any gene of SEQ ID NO: 1 or having homology to SEQ ID NO: 1 (pg 9, lines 1-4). However, not all genes sharing homology with SEQ ID NO: 1 are GPRC5-like genes. For example, FPR-RS1, FPR-RS2 and FPR-RS3 genes share homology with SEQ ID NO: 1, but are not FPR-RS4 genes.

Applicants argue the term is clear because those of skill would know what genes are FPR-RS4 genes. Applicants' argument is not persuasive because of the confusing definition of FPR-RS4 genes.

Claim Rejections - 35 USC § 103

The rejection of claims 3-9, 14 and 22 under 35 U.S.C. 103(a) as being unpatentable over Gao (1999, J. Exp Med, Vol. 189, pg 657-662) in view of Gao (1998, Genomics, Vol. 51, pg 270-276) has been withdrawn in view of the amendment.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER